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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/786,907	02/25/2004	Bjame Bogen	2600-000003	6743

27572 7590 11/16/2007  
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EXAMINER
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BRISTOL, LYNN ANNE

ART UNIT	PAPER NUMBER
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1643

MAIL DATE	DELIVERY MODE
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11/16/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Advisory Action</b> <b>Before the Filing of an Appeal Brief</b>	<b>Application No.</b> 10/786,907	<b>Applicant(s)</b> BOGEN ET AL.	
	<b>Examiner</b> Lynn Bristol	<b>Art Unit</b> 1643	

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 19 October 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.  
 b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

#### AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
 (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);  
 (b) ☐ They raise the issue of new matter (see NOTE below);  
 (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
 (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
 5. ☒ Applicant's reply has overcome the following rejection(s): 112, 2<sup>nd</sup> paragraph (in part) [IF, IF ENTERED].  
 6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
 7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
 The status of the claim(s) is (or will be) as follows:  
 Claim(s) allowed: \_\_\_\_\_  
 Claim(s) objected to: \_\_\_\_\_  
 Claim(s) rejected: 83, 88-92, 95, 96, 98-100 and 118-126.  
 Claim(s) withdrawn from consideration: 1-37, 77, 84-87, 93, 94, 97, 101-108.

#### AFFIDAVIT OR OTHER EVIDENCE

8. ☒ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
 9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
 10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

#### REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
See Continuation Sheet.  
 12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). \_\_\_\_\_  
 13. ☐ Other: \_\_\_\_\_

  
**LARRY R. HELMS, PH.D.**  
**SUPERVISORY PATENT EXAMINER**

Continuation of 11. does NOT place the application in condition for allowance because:

The rejection of Claims 83, 88-92, 95, 96, 98-100, 118-126 is maintained under 112, 2nd paragraph because "a hinge region" can be any flexible region obtained from any molecule including an immunoglobulin. For example, cancelled Claim 110 was drawn to where the hinge is from Ig.

The 102(e) rejection of Claims 83, 88-92, 96, 98, 119, 120 and 123 over Herman is maintained because Applicants have yet to distinguish the spatial relationship of the elements of the construct of Claim 83 over the elements of Herman. The instant nucleic acid encoding the monomer unit comprises an antigenic unit and a targeting unit for an APC where each monomer unit lack a CH2 domain. The claim does not define how the dimerization motif comprising a hinge region and a Cgamma3 domain is spatially related to a nucleic acid encoding the monomer unit. Is the dimerization motif also encoded by the nucleic acid encoding each monomer unit? The dimerization motif is described for the antibody-based dimeric molecule, but the claim does not recite the relationship of the dimerization unit to the antigenic unit and targeting unit with respect to the nucleic acid much less the spatial relationship of the dimerization unit, antigenic unit and targeting unit within the nucleic acid. It is possible that the dimerization unit is expressed by a different nucleic acid than that encoding the monomer unit.

The rejection of Claims 118, 121, 122, and 124-126 under 112, 1<sup>st</sup> paragraph is maintained. Applicants have cited three references on p. 23 of their response in support of the allegation that the MOP315.4 cell line is art recognized as a multiple myeloma antibody model. No copies of the three references (Eisen, Schulenburg and Eison) are included with the filed response. The references would otherwise require further grounds for consideration. Additionally, even if copies were provided, Applicants have not established why the evidence was not timely submitted for consideration. Applicants have also provided copies of three references (Brunsvik, Schjetne, and Fredriksen) alleging that DNA vaccine compositions could produce prophylactic and preventative effects. Again, Applicants have not established why the evidence was not timely submitted for consideration.

The rejection of Claims 118, 121, 112 and 124-126 under 112, 1<sup>st</sup> paragraph is maintained. Applicants' allegations on pp.28-31 of the Response indicate that the monomer unit is expressed from a single expression vector and that two monomer units would be expressed in sufficient amount in vivo in order to dimerize into a functional antibody-based dimeric molecule. It is understood that in order for the antibody to operate, two monomeric units must dimerize. The only working example for a DNA vaccine uses the MOP315.4 cell line and as discussed above, Applicants response is deficient for copies of the references allegedly supporting the cell line as a clinically relevant animal model.

Finally, it is noted that on p. 18 of the Response, Applicants indicate Claims 83, 88-92, 95, 96, 98-100, 110, 111 and 113-126 are all the claims under examination. However, in the claim set of 10/19/07, Claims 113-117 are cancelled.